JAN 1 8 2005

K043576

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
For Dimension® RxL Max™ Clinical Chemistry System with Automation System

1. Manufacturer and Contact Information:

Manufacturer: Dade Behring Inc.
101 Silvermine Road.
Brookfield, CT 06904

Contact Information: Stanley P. Gorak.
Quality Systems and Compliance Manager
Dade Behring, Inc.
500 GBC Drive, M/S 514
P.O. Box 6101
Newark, DE 19714-6101
Tel: 302-631-7458
Fax: 408 -631-6299

2. Date Summary Prepared:
December 16, 2004

3. Device Trade Name/ Common Name:
Dimension® RxL Max™ / StreamLAB® Analytical Workcell/ Sample Transfer Module

4. Device Classification Name:
Analyzer, chemistry (photometric, discrete), for clinical use has been classified as Class I, JJE by the Clinical Chemistry and Clinical Toxicology Devices Panel, (21 CFR 862.2160). No performance standards have been established under Section 514 of the Food, Drug, and Cosmetic Act.

5. Intended Use:
The Dimension RXL Max™ clinical chemistry system with automation system is a discrete, random-access, microprocessor-controlled, integrated instrument/chemistry system that measures a variety of analytes, including enzyme activities, in body fluids. It can also process high-sensitivity chromium-based heterogeneous immunoassays with its HM module.

6. Device Description:
The modified device includes the connection of a StreamLAB® Analytical Workcell and Sample Transfer Module. These are used to prepare specimens from the human body for testing on the Dimension® RxL Max™ system.

7. Substantial Equivalence

The modified device has the same operating principles, design, manufacturing materials, method of manufacture, assay performance characteristics and intended use as the predicate device. In conclusion the modified Dimension® RxL Max™ with automation system is substantially equivalent to the predicate Dimension RxL Max™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 18 2005

Mr. Stanley P. Gorak, Jr.
Quality Systems and Compliance Manager
Dade Behring Inc.
500 GBC Drive, M/S 514
P.O. Box 6101
Newark, DE 19714-6101

Re: k043546
Trade/Device Name: Dimension® RxL Max™ with StreamLAB® Analytical Workcell and Sample Transfer Module
Regulation Number: 21 CFR 862.1770
Regulation Name: Urea nitrogen test system
Regulatory Class: Class II
Product Code: CDQ, CDT, CEC, CEK, CEM, CEO, CFJ, CFQ, CFR, CGS, CGX, CGZ, CHH, CHI, CIC, CIG, CIT, CJE, CJW, CKA, CKE, CZW, DBI, DCF, DCN, DDG, DDR, DHA, DIH, DIO, DIP, DIS, DJG, DJR, DKJ, DKZ, DLZ, DMJ, JFJ, JFL, JGJ, JHC, JHM, JHT, JHY, JIF, JIH, JJE, JLW, JMG, JMO, JQB, JXM, KHP, KHQ, KHS, KLB, KLI, KLR, KLS, KLT, KXT, LAN, LAR, LCD, LCM, LCP, LDJ, LDP, LEG, LEH, LFM, MKW, MMI, MRR, NBC
Dated: December 21, 2004
Received: December 23, 2004

Dear Mr. Gorak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (If Known):

Device(s) Name(s):

Dimension® RxL Max™ with StreamLAB® Analytical Workcell and Sample Transfer Module

Indications for Use:

The Dimension® RxL Max™ with StreamLAB® Analytical Workcell and Sample Transfer Module is a discrete photometric chemistry analyzer for clinical use intended to duplicate analytical procedures by performing automatically various steps such as pipetting, preparing filtrates, heating, and measuring color intensity. This device is intended for use in conjunction with certain materials to measure a variety of analytes.

Prescription Use ✓ **and/or** **Over-the-counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K043546